K080257

MAY 22 2008

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
MicroFrance Laparoscopic Manual Surgical Instruments, various

510(k) Owner	Medtronic Xomed, Inc. 6743 Southpoint Drive North Jacksonville, Florida 32216-0980 USA 904-296-9600 904-296-2386 (FAX)
Contact Name	Jayme Wilson Senior Regulatory Affairs Specialist Medtronic Xomed, Inc.
Date Summary Prepared	January 30, 2008
Proprietary Name	MicroFrance Laparoscopic Instruments, various
Common Name	Laparoscopic Instruments, General and Plastic Surgery
Classification Name	Laparoscope accessories, Endoscopic procedures (21 CFR 876.1500, Product Code GCJ, Class II) Laparoscope accessories, Gynecologic procedures (21 CFR 884.1720, Product Code HET, Class I)

Marketed device claiming equivalence to

MicroFrance Laparoscopic Instruments are equivalent to Geister Medizintechnik GMBH GIMMI ALPHA Gastro-Urology, & Laparoscopic Endoscopes, Endoscopic Accessories – K012660, Allegiance Healthcare Corp Modular Laparoscopic Grasping Forceps, Scissors – K991928, MicroFrance Electrosurgical Instruments – K993655, and MicroFrance Laparoscopic Manual Surgical Instruments for gynecological use.

Device Description

The subject instruments include a full line of laparoscopic manual surgical instruments and accessories for various laparoscopic intended uses.

Intended Use

Manual surgical instruments are intended for use in a wide variety of surgical procedures including various laparoscopic and endoscopic procedures. The instruments are intended to scrape, cut, grasp, hold, remove, or manipulate tissue or structures.

Comparison to Marketed Devices

	Medtronic Xomed, Inc. MicroFrance Laparoscopic Manual Surgical Instruments, various PROPOSED	Medtronic Xomed, Inc. MicroFrance Laparoscopic Manual Surgical Instruments for Gynecologic Use (Class I exempt)	MicroFrance Electrosurgical Instruments, Various K993655	Geister Medizintechnik GMBH GIMMI ALPHA Gastro-Urology, & Laparoscopic Endoscopes, Endoscopic Accessories K012660	Allegiance Healthcare Corp Modular Laparoscopic Grasping Forceps, Scissors K991928.
Intended Use	Manual surgical instruments are intended for use in a wide variety of surgical procedures including various laparoscopic and endoscopic procedures. The instruments are intended to scrape, cut, grasp, hold, remove, or manipulate tissue or structures	The manual surgical instruments are intended for use in various Gynecological laparoscopic procedures. The instruments enable a surgeon to grasp, manipulate, dissect, retrieve, biopsy, or cut internal tissue or organs.	The electrosurgical instruments are intended to remove tissue and control bleeding. The instruments consist of scissors, forceps, and probes available in configurations for laparoscopic/ endoscopic access and open field surgery.	Intended to be used by qualified physicians to provide access, illumination and visualization of internal structures and for manipulating soft tissue (grasping, cutting, coagulating, dissecting, and suturing) in a wide variety of diagnostic and therapeutic laparoscopic/urologic closed and minimally invasive procedures.	The Allegiance Modular Endoscopy Laparoscopic Scissors, Grasping Forceps, Dissectors and Needle Holders are used as accessories in general laparoscopic diagnostic and surgical procedures for manipulating tissue (grasping, cutting, dissecting, coagulating and suturing).
Material	Stainless Steel Tungsten (Needle Holders) Insulation material	Stainless Steel Insulation material	Stainless Steel Insulation material	Stainless Steel Insulation material	Stainless Steel Insulation material
Diameter Lengths	3mm to 12mm Tube, various from 25cm to 60cm	3mm, 5mm, 10mm Tube, various from 25cm to 45cm	3mm, 5mm, 10mm Tube, various from 25cm to 45cm	5mm Tube, various, from 25cm to 38cm	3mm, 5mm, 10mm, 11mm Tube various, 32cm to 45cm
Types of Devices	Dismantable and Non-dismantable Insulated and non-insulated Forceps, Probes, Needle Holders, Clamps, Dissectors, Scissors, Knives, Hooks, Knot Guides, Retractors, and Blades	Dismantable and Non-dismantable Insulated and non-insulated Forceps, Probes, Needle Holders, Clamps, Dissectors, Scissors, Hook, Knot Guide, and Blades	Dismantable and Non-dismantable Insulated scissors, forceps, and probes	Dismantable and Non-dismantable Insulated and non-insulated Forceps, Probes, Needle Holders, Clamps, Dissectors, Scissors, Knife, Hook, Knot Guide, Retractors, Divers and Blades	Modular and Non-Take Apart Insulated and non-insulated Dissectors, Forceps, Graspers, Scissors, Needle Holders, Retractors
Sterility	Distributed non-sterile	Distributed non-sterile	Distributed non-sterile	Distributed non-sterile	Distributed non-sterile
Reusable	Yes	Yes	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2008

Medtronic Xomed, Inc.
% Jayme Wilson
Senior Regulatory Afairs
Specialist
6743 Southpoint Drive North
Jacksonville, Florida 32216

Re: K080257
Trade/Device Name: MicroFrance Laparoscopic Manual Surgical Instruments, various
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: HET, GCJ
Dated: April 17, 2008
Received: May 6, 2008

Dear Jayme Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K080257/S1

Device Name: MicroFrance Laparoscopic Manual Surgical Instruments, various

Manual surgical instruments are intended for use in a wide variety of surgical procedures including various laparoscopic and endoscopic procedures. The instruments are intended to scrape, cut, grasp, hold, remove, or manipulate tissue or structures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080257